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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,811	06/29/2001	Thomas D. Madden	16303-008020	7024

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EXAMINER

LEWIS, AMY A

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,811

Applicant(s)

MADDEN ET AL.

Examiner

Amy A. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5 and 27-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,27,28,30,37-40 and 43 is/are rejected.
- 7) ☒ Claim(s) 37-40, 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5 May 2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 April 2005 has been entered.

Disposition of the Claims

Claims 13-15, 17 and 26 have been cancelled and re-presented as new claims 32-34, 36, and 35 respectively. Currently, claims 1, 2, 4, 5, and 27-43, as filed on 28 April 2005 are pending.

Applicant's arguments will be addressed as follows:

Claim Objections

Claims 7-9, 11-15, 17, and 26 stand objected to because the claim set currently presented does not match the previously presented claims set. This objection is ***withdrawn*** in view of the cancellation and re-presentation of the new claims.

Art Rejections - 35 USC §§ 102 & 103

1) The rejection of claims 1, 2, 4, 5, and 23 under 35 USC § 103 as being unpatentable over Madden et al. was withdrawn (in the office action dated 4/28/2004) in view of Applicant's

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arguments. This rejection will **not** be applied to the corresponding new claim 36, also in view of Applicant's arguments.

2) The rejection of claims 1, 2, 4, 5, and 23 under 35 USC § 103 as being unpatentable over Madden et al. in view of Omrod et al. was withdrawn (in the office action dated 4/28/2004) in view of Applicant's arguments. This rejection will **not** be applied to the corresponding new claims 27-30 and 35, also in view of Applicant's arguments.

3) In reference to re-presented claims 31-34 and 36, Applicant argues that these claims are also non-obvious in light of Madden and Omrod, for the reasons stated previously in the remarks filed 19 November 2003 (p. 6-9) which were found persuasive by the Examiner regarding the corresponding and now cancelled claims. The Examiner agrees and finds these arguments persuasive. Therefore, a rejection of Madden and/or Omrod under 35 USC §§ 102 or 103 will **not** be applied to claims 31-34 and 36.

Double Patenting Rejection

Claims 1, 2, 4, 5, and 17 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-35, 37, 39-57, and 60-63 of copending Application No. 09/896,812. This rejection is withdrawn over claim 17 in view of cancellation of the claim. This rejection is ***maintained*** and newly applied to claim 36 (which corresponds to cancelled claim 17), and 37-40 (which correspond to claims 1, 2, 4, and 5, except the phrase "about" is removed regarding the numerical ranges).

Applicants argue that "the claimed invention is not obvious in light of the claims of the copending Application No. 09/896,812" and that "the claims of the instant application are drawn

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to liposomal topotecan unit dosage forms, said dosage forms comprising *specific dosages*” (Applicant’s response p. 9, 2nd paragraph, emphasis added).

As stated in the previous office actions (the Final Rejection mailed 4/28/2004) and the Advisory Action, mailed 22 September 2004, although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to liposomal formulations comprising camptothecin and/or topotecan compounds. And, as stated in the Advisory Action, that changes in variables are not patentable where the difference is one of degree; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. Regarding claims 37-40, removal of the term “about” from the claim language does not render the claims patentable. See for example *In re Aller* 105 USPQ 233. Here, the selection of appropriate dosages would appear to require the application of no more than routine skill in the art.

In summary, claims 1, 2, 4, 5, and 37-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-35, 37, 39-57, and 60-63 of copending Application No. 09/896,812. This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not been patented.

The following new rejections will be set forth:

Claim Rejections - 35 USC § 102(b)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Madden et al. The examiner acknowledges that rejection of claims 6 and 7 as being unpatentable over Madden et al. was withdrawn in view of their cancellation. Because claim 27 is a re-presentation of claim 7, the rejection now applies.

As stated in the office action (dated 11/19/2003, page 4), Madden et al. teach a lipid-based carrier formulation which differs from earlier liposomes in that topotecan is trapped in the aqueous interior of the carries. The reference teaches topotecan is stable in plasma and that even 24 hours after injection, the topotecan remaining in the circulation carriers is almost 90% lactone. Therefore, Madden clearly teaches a liposomal topotecan formulation as claimed instantly in claim 27. (See abstract).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant has acknowledged that the rejection of claims 8, 10, and 11 under 35 USC § 103(a) as being unpatentable over Madden et al. in view of Slater et al. (US Pat. 6,355,268) has been withdraw, in a previous office action, in view of cancellation of claims 8, 10, and 11. Applicant asserts that "these claims are not presented as new claims in the present amendment."

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The Examiner disagrees. New claims 28 and 30 are re-presented as substantial duplicates of and correspond to cancelled claims 8 and 11, respectively. Therefore, claims 28 and 30 are now rejected under 35 U.S.C. 103(a) as being unpatentable over Madden et al. in view of Slater et al. (US Pat. 6,355,268), for the reasons stated in the previous office action dated 11/19/2003 (pages 8-10).

Claim Objections

Claim 37 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1.

Claim 38 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2.

Claim 39 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 4.

Claim 40 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5.

Claim 43 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 36.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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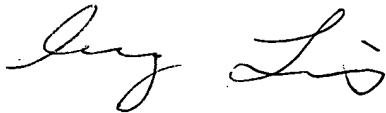
Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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